NATO

Economic Impact of Proposed FDA Tobacco Deeming Regulations on Tobacco Retailers

1. Traditional Tobacco Stores Will Lose on Average $130,000 in Pipe Tobacco Sales

A. Tobacconist store retailers rely on pipe tobacco sales for approximately 20% of total store sales. Retailers that blend different pipe tobaccos together may be required to register with the FDA as a manufacturer.

B. Cost for a retailer to comply with FDA manufacturer requirements would be excessive (i.e., facility registration, ingredient disclosure, harmful constituent reporting, FDA inspections, good manufacturing practices, marketing restrictions, and product standards).

C. Tobacco store retailers do not have the expertise to register as a manufacturer and comply with manufacturer requirements, causing retailers to cease pipe tobacco blending.

D. 1,500 tobacco store retailers x $130,000 in lost sales/store = $195,000,000 impact.

E. Employment Impact: Minimum of two employees lost per store = 3,000 lost jobs.

F. Was the FDA supposed to include in the fiscal impact analysis of the agency's tobacco deeming regulations the financial cost of retailers having to register as a manufacturer and comply with manufacturer regulations? If so, it does not appear that the FDA provided such a fiscal analysis.

F. A solution that was proposed by NATO in its comments on the tobacco deeming regulations is to exempt tobacco retail stores that blend less than 5,000 pounds of pipe tobacco annually from the manufacturing registration and compliance requirements.

2. Predicate Date Needs to be Changed to Avoid Anti-Competitive Marketplace

A. The Family Smoking Prevention and Tobacco Control Act set February 15, 2007 as the predicate or grandfather date for existing tobacco products and the deeming regulations retain this date.

B. Small, medium and large manufacturers of hundreds of cigars, pipe tobacco products and electronic cigarettes would be required to compile and submit Pre-Market Tobacco Applications (PMTA) to the FDA to keep products on the market since similar products were not on the market as of February 15, 2007.

C. The Wall Street Journal reported on July 7, 2015 that a single PMTA application could cost between $2 million and $10 million per tobacco product, which means that the cost would be prohibitive for many tobacco manufacturers to compile and submit PMTA applications effectively forcing products out of the market.

D. If thousands of cigar, pipe tobacco and e-cigarette products are removed from the marketplace, the dollar sales loss for retailers would be in the billions of dollars.

Department of Treasury Tax Paid Tobacco Products (12 Months Ending 11/2015)

Number of Cigars (Large):	4,556,000,000
Number of Cigars (Small/Little):	368,403,058
Pipe Tobacco (Pounds):	25,418,292
Electronic Cigarettes (Dollar Sales):	$ 2,000,000,000

Federal Excise Taxes Collect on Tobacco Products: $14,000,000,000

E. The U.S. Treasury would collect substantially less in federal excise taxes if manufacturers do not file PMTAs and it appears that the FDA economic impact analysis did not include an estimate of reduced federal tobacco excise tax collections or state tobacco excise tax collections.

F. The result would be an anti-competitive marketplace since only several large manufacturers in each of the deemed tobacco product categories would have the financial ability to compile and submit PMTA applications.

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2014-N-0189

Dear FDA Representative:

The National Association of Tobacco Outlets, Inc. (NATO) submits these comments in response to the Food and Drug Administration's Proposed Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as published in the Federal Register at 79 Fed. Reg. 23142 on April 25, 2014.

Minimum Age of Purchase: The minimum age to purchase deemed tobacco products would be 18 years old and retailers will be required to verify through photographic identification the legal minimum age of a customer who is younger than 27 years old.

Retailers support a minimum age of 18 years old to purchase cigars, pipe tobacco, electronic cigarettes, hookah tobacco, dissolvables, and nicotine gels. This is the same minimum age required for the purchase of cigarettes, roll-your-own tobacco, and smokeless tobacco products at the state level, except for Alabama, Alaska, New Jersey and Utah, which have a minimum age of 19.

Establishing a minimum legal age for purchasing the deemed tobacco products is an issue of responsibility. Retailers are responsible people who are not in the business of selling tobacco products to minors.

Also, retailers support requiring age verification through photo identification of a customer who is younger than 27 years old. Retailers are accustomed to complying with this age verification requirement for cigarettes, roll-your-own, and smokeless tobacco products and continuing the policy for the deemed tobacco products is both appropriate and efficient, as retailers will train their staff with a single procedure for requiring photo identification and age verification.

Definition of Premium Cigar: Under the proposed deeming regulations, a premium cigar is defined as a cigar that: (1) is wrapped in whole tobacco leaf, (2) contains a 100% tobacco leaf binder, (3) contains primarily long filler tobacco, (4) is made by combining manually the wrapper, filler and binder, (5) has no filter, tip or mouthpiece, (6) has a retail price of at least $10 per cigar, (7) does not have a characterizing flavor other than tobacco, and (8) weighs more than 6 pounds per 1,000 cigars.

Of the eight different factors listed by the FDA to define a premium cigar, the appropriate definition of a premium cigar should include the following factors: (1) being wrapped in whole tobacco leaf, (2) containing 100% tobacco, (3) is made by hand-rolling, (4) has no filter, tip or mouthpiece, and (5) has a specified minimum weight per 1,000 cigars.

Setting a minimum manufacturer's suggested retail price of $10 per cigar is unrealistic, arbitrary and capricious because: (1) not all manufacturers have a minimum suggested retail price, (2) the retail price of a cigar will vary from state to state due to differences in state excise taxes, and (3) a significant majority of premium cigars have a retail price below $10, with many premium cigars priced substantially less than $10 per cigar.

To establish a minimum uniform weight for premium cigars, the FDA should look to state laws that establish a weight per thousand cigars. The highest weight for premium cigars under a state law is Minnesota where large cigars would need to weigh 4.5 pounds or more per thousand. This is the weight that should be used in defining a premium cigar in place of the "more than 6 pounds per thousand" standard.

Premium cigars are not a standardized product, but are manufactured in many different sizes, shapes, tobacco blends, or flavors. The variation in tobacco blends used in making premium cigars means that approximately 90% of these cigars could be considered to have a characterizing flavor other than the allowed "tobacco" flavor. This means that banning cigar flavors, other than tobacco, would result in a ban on the sale of the vast majority of premium cigars. As a result, family-owned retail businesses that sell premium cigars would lose a substantial amount of cigar sales, causing job loss and the closure of specialty tobacco stores. What would flourish is a black market for contraband premium cigars. A federal agency should not adopt a regulation that financially impacts law-abiding manufacturers, wholesalers and retailers while creating the conditions for a black market, and even exacerbating a black market that already exists in the United States for premium Cuban cigars.

Registration and Ingredient Disclosure: Manufacturers of deemed tobacco products must register each of their tobacco manufacturing facilities with the FDA, submit a product list, file a list of ingredients, and report any harmful and potentially harmful constituents.

Many tobacco retailers that sell pipe tobacco will blend two or more pipe tobaccos together to develop different flavors of pipe tobacco. Since the primary manufacturer would have already registered the pipe tobaccos that are being blended together, the question arises whether tobacco retailers that blend registered pipe tobaccos would also be considered a "manufacturer" for product registration, product ingredient disclosure, and harmful and potentially harmful constituent reporting.

With the significant time and cost involved in registering tobacco products and filing ingredient lists for each different pipe tobacco blend, a tobacco retailer would not have the expertise or financial ability to compile these filings and conduct the tests to comply with the manufacturer requirements. This means that tobacco retailers would be prohibited from blending pipe tobaccos resulting in a substantial loss of pipe tobacco sales and devastate small retail businesses that have for decades sold pipe tobacco to a loyal base of adult customers.

The FDA's Center for Tobacco Products should consider providing an exemption to allow tobacco retailers to blend an aggregate of up to 5,000 pounds of pipe tobacco a year without the retailer being subject to pipe manufacturer regulations provided that the primary manufacturers of pipe tobaccos have already complied with all FDA regulations including, but not limited to, product registration, ingredient listing, and HPHC filings. To require both the primary manufacturer and a tobacco retailer to register pipe tobaccos and file product ingredient lists would be redundant. Pipe tobaccos blended together retain their same characteristics after the blending occurs, except for a new flavor when smoked in a pipe. Since the FDA is not proposing to regulate pipe tobacco flavors, and that is the only characteristic that changes when pipe tobaccos are blended, then retailers that blend pipe tobacco should not be considered manufacturers of pipe tobacco.

In the event that the FDA would require retailers that blend pipe tobaccos to be considered manufacturers, then retailers would be forced to choose between no longer selling blended pipe tobacco or selling the proper amount of the different pipe tobaccos in separate sealable bags with instructions for the customer to take the bags home, open the bags, and mix the different pipe tobaccos together to obtain the blended pipe tobacco product. This situation will only create an inconvenience for customers and cause retailers who want to save their business to resort to the alternative method of selling separate bags of pipe tobacco to customers to avoid being regulated as a manufacturer. Retailers want to comply with the law, but the laws need to be fair and reasonable.

The FDA has not included in the agency's fiscal impact assessment on small companies the possibility that retailers that blend pipe tobaccos would be considered manufacturers requiring product registration, ingredient disclosure, and HPHC disclosure. This is a requirement of the rulemaking process and the costs to retailers would be significant. The FDA needs to correct its fiscal impact assessment and include the impact on small, family-owned retail stores that blend pipe tobacco.

Prohibition on Descriptors: The deeming regulations provide that modified risk descriptors such as "light," "low," and "mild" cannot be used to describe a regulated tobacco product. Regarding pipe tobacco, certain descriptive words are used to describe a blend of pipe tobacco such as "mild". However, in contrast to the use of the descriptor "mild" for cigarettes, the term "mild" when applied to pipe tobacco does not mean that there is less risk or the product is less harmful. Rather, the term relates to the pipe tobacco's flavor and the fact that the pipe tobacco does not have a bite or harshness when smoked.

Ban on Free Samples: The deeming regulations propose prohibiting giving free samples of the deemed tobacco products. The FDA's Center for Tobacco Products has recognized that there is

a continuum of risk for tobacco products with some tobacco products like combustible cigarettes on one end of the risk spectrum and electronic cigarettes potentially near the other end of the spectrum.

With the deemed tobacco products being less harmful, then adult consumers should be allowed to sample less harmful products and not be discouraged from transitioning to such less harmful products. These less harmful tobacco products include electronic cigarettes.

The sampling of these deemed tobacco products is a retail tradition and is essential for adult consumers to try new and different tobacco products. As a general rule, sampling of cigars and pipe tobacco occurs in tobacco speciality stores. For example, manufacturers will assist retailers in holding special cigar tasting and pipe tobacco sampling events, much like a wine tasting event at a liquor store. These speciality tobacco stores do not allow minors to be present in the store. With no minors having access to these events, sampling of cigars and pipe tobacco should also be allowed.

Premarket Review: For the deemed tobacco products that were not on the market as of February 15, 2007, manufacturers of these products would need to submit a premarket tobacco application (PMTA) to the FDA within 24 months following the effective date of the final deeming regulations. If a PMTA application is filed with the FDA during this 24-month period, then the manufacturer can continue to market its products unless and until the FDA responds to the application.

The pre-market application process will be costly and time consuming for manufacturers and will likely result in many different kinds of deemed tobacco products being removed from the marketplace. Cigars come in numerous shapes and sizes with variations in cigar tobacco as well as limited manufacturing of special edition cigars and seasonal blend cigars. This constant variation in the cigar tobacco used to make premium cigars and the limited number of cigars manufactured for special editions and seasonal blends will create significant regulatory burdens and costs for cigar manufacturers to be constantly filing pre-market tobacco applications. Those cigar manufacturers that are unable to bear the cost of pre-market tobacco applications will cease bringing new products to the marketplace.

Pipe tobacco manufacturers will incur the same cost and time burdens if they were required to file pre-market tobacco applications for each new blend of pipe tobacco that they manufacture.

Regarding electronic cigarettes, since there were no similar products on the market prior to February 15, 2007, each electronic cigarette manufacturer would need to file a pre-market application for every brand of electronic cigarette currently being sold and new electronic cigarettes introduced into the marketplace. Small manufacturers may not have the financial resources to file pre-market applications resulting in the removal of electronic cigarettes from the marketplace.

The end result of the pre-market tobacco application process will be the significant negative impact on family-owned retail stores who will no longer be able to provide the tobacco products that their adult customers request. This loss of sales will cause a financial hardship for many

retailers, which could lead to job loss and even retail store closures. Congress did not intend through the passage of the Family Smoking Prevention and Tobacco Control Act to cause hard working Americans to lose their jobs or their entire businesses.

Substantial Equivalency: In the proposed deeming regulations, the FDA states that it does not have the authority to amend the statutory grandfather date of February 15, 2007 established by Congress under the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") for marketing tobacco products that are substantially equivalent to other products that were in the marketplace prior to this grandfather date. In fact, in the proposed rule, the FDA asks, "Are there other legal interpretations of the substantial equivalence grandfather provision that FDA should consider?"

NATO believes that the FDA has the regulatory and enforcement discretion to adopt a new grandfather date for the substantial equivalency product pathway under Section 701(a) of the Food, Drug and Cosmetic Act. This provision authorizes the agency to draft regulations for the "efficient enforcement" of laws to carry out the intent of Congress. In the Tobacco Control Act, Congress authorized the FDA to regulate tobacco products, including any deemed products, but specifically prohibited the FDA from banning cigarettes, smokeless tobacco products, cigars, pipe tobacco, and roll-your-own tobacco. [See Section 907(c)(3) of the Tobacco Control Act].

However, if the FDA relies on the February 15, 2007 grandfather date, many newer deemed tobacco products may not be substantially equivalent to those tobacco products that existed in the marketplace prior to February 15, 2007, thus effectively banning these newer tobacco products. Such an outcome is contradictory to the Congressional intent that tobacco regulations not be proposed or adopted by the FDA that would ban tobacco products. Therefore, the "efficient enforcement" of the Tobacco Control Act cannot include regulations that would literally remove legal tobacco products from the marketplace.

The legal theory of "equity" can be relied on the FDA to adopt a new grandfather date for substantially equivalent tobacco products. Equity is based on what is fair in a particular situation rather than relying on a strict interpretation of a statute or regulation. When considering and debating the Tobacco Control Act, Congress could not have intended that the FDA would be forced to prohibit the sale of legal tobacco products that were introduced in the marketplace after February 15, 2007. From an equitable and fairness point of view, newer tobacco products should be given the *same* or *similar* treatment as cigarettes, roll-your-own tobacco, and smokeless tobacco products were provided when the Tobacco Control Act took effect in June of 2009.

If the FDA treats newer tobacco products ***the same as*** cigarettes, roll-your-own tobacco, and smokeless tobacco, then under its enforcement discretion, the agency could establish a new grandfather date for deemed tobacco products that is 28 months prior to the effective date of the deeming regulations. When the Tobacco Control Act was enacted in June of 2009, the grandfather date at that time for substantially equivalent products was 28 months earlier, namely in February of 2007. If this same 28-month period of time is relied on for a new grandfather date, then, for example, a deeming regulation that takes effect on August 1, 2015 would have a new grandfather date of April 1, 2013, which is 28 months earlier.

If the FDA treats newer tobacco products in ***a similar fashion,*** especially given the very recent market introduction of such new products as electronic vaping products including electronic cigarettes, then the agency could also consider the effective date of the deeming regulations as the grandfather date. Under this option, the FDA would ensure that the substantial equivalency pathway was a viable option for the broadest range of newer tobacco products, especially those that are potentially less harmful and may have been introduced in the marketplace very recently.

Under either new grandfather date, the FDA would be exercising regulatory flexibility to ensure the efficient enforcement of the Tobacco Control Act when no one, including the members of Congress, could have foreseen five years ago in 2009 the development of such products as the electronic cigarette and other potentially less harmful tobacco products. Leaving the grandfather date as February 15, 2007 could very well result in the removal of hundreds of otherwise legal tobacco products from store shevles that adult consumers desire to purchase and use.

Health Warnings: The FDA is proposing to require a new health warning on all deemed tobacco products, on all cigarette tobacco and roll-your-own tobacco packaging, and all advertisements for these tobacco products. This warning would read: "WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical." Under Option 2, this warning would not be required on premium cigars.

The current Surgeon General health warnings on cigarette packages were the result of Congressional passage and subsequent enactment of the Federal Cigarette Labeling and Advertising Act. Similarly, the current health warnings on smokeless tobacco products were enacted due to passage of the Comprehensive Smokeless Tobacco Health Education Act of 1986, which was subsequently amended by the Family Smoking Prevention and Tobacco Control Act. Also, the cigar health warnings were the result of a legal settlement between seven cigar manufacturers and the Federal Trade Commission.

The Family Smoking Prevention and Tobacco Control Act does not specifically authorize the FDA to require health warnings on any of the deemed tobacco products. Given that all of the other current health warnings on cigarettes, smokeless tobacco products, and cigars arose out of Congressional action or the settlement of legal action, the FDA does not have express authority to mandate new health warnings for the deemed tobacco products. For this reason, the proposed health warning should not be required to be displayed on the packaging of deemed tobaccos.

Tobacco Product Flavors: The proposed deeming regulation does not ban flavors for the deemed tobacco products. The ban on flavors, except tobacco and menthol, continues to only apply to cigarettes. However, the FDA is requesting comments on factors it should consider in determining whether a particular tobacco product such as a little cigar or other non-cigarette tobacco product could be characterized as a "cigarette" and thus subject to the current flavor ban.

In the absence of Congressional action to extend a ban on flavors to tobacco products other than cigarettes, the FDA's request for input on whether a tobacco product such as a little cigar or other non-cigarette tobacco product could be characterized as a "cigarette" and subject to the current flavor ban is overreaching Every kind of tobacco product is individually defined under federal law and this request by the FDA is an attempt to redefine various tobacco products as if

they are cigarettes in order to impose flavor restrictions. The FDA is not a legislative body and, for that reason, cannot change legal definitions of tobacco products under federal law to facilitate a regulation banning certain flavors.

NATO appreciates the opportunity to submit these comments in response to the proposed deeming regulations.

Sincerely,

Thomas A. Briant

NATO Executive Director and Legal Counsel